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| 10/031,757 | 01/17/2002 | Hans Strandberg | P01,0581 | 8338 |

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EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT PAPER NUMBER

3762

DATE MAILED: 02/11/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,757

Applicant(s)

STRANDBERG, HANS

Examiner

Carl H. Layno 2/9/04

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 20 is/are rejected.
- 7) ☒ Claim(s) 13-19 and 21-24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgment is made of applicant's preliminary amendment which was received by the Office on January 17, 2002. This document has been made of record in the file as part of Paper No.1.

2. Claims 1-11 are canceled. Claims 12-24 have been added and are active.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file as Paper No.2.

4. Receipt is also acknowledged of priority papers submitted under 35 U.S.C. 371, which papers have been placed of record in the file. This case claims priority filing based upon PCT application PCT/SE00/01307, filed June 19, 2000.

Information Disclosure Statement

5. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449) which was received by the Office on January 17, 2002. This document has been made of record in the file as Paper No.3.

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Drawings

6. Applicant's formal drawings have been objected to by the Draftsperson. See the attached PTO-948 for comments.

Specification

7. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to **a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.** The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The Abstract in this case is over 200+ words in length.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

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reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 12 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Mann et al '717 or Lu '192 (Applicant's prior art).

The Mann et al '717 patent describes an implantable dual-chambered atrial pacemaker (Fig.1) having circuits for detecting atrial tachycardia which read upon applicant's claimed features. Specifically, the Mann et al pacer comprises an atrial detector/P-wave sensing amplifier **22**, a ventricular/R-wave sensing amplifier **24**, stimulation circuits **18,20**, and a control system **26**, which performs the duty of applicant's claimed comparator, mode switching unit, and cardiac event interval determination unit. Applicant's attention is directed to Figs.6A-7, which shows the comparator function when the atrial rate is measured (block **106**) and compared to an atrial tachycardia detection rate (ATDR) (block **108**). When this rate is exceeded (i.e. the P-P interval is shorter), the control system **26** switches the pacing mode to a non-tracking mode called a "non-atrial synchronous mode" **152** (Fig.6B). Note that the algorithm employs a "predetermined count limit" of between 3 and 5 cardiac cycles during which time the P-P intervals are monitored for stability (col.17, lines 44-47). The control system **26** performs the duty of applicant's "cardiac event interval determination unit" by calculating appropriate ventricular stimulation (V-V) interval values (Fig.7 – see block **192**) and pacing in a non-atrial synchronous mode pacing **164** (Fig.6B). Upon detection of an atrial rate below a maximum tracking rate (MTR), the pacer switches modes back to an atrial synchronous tracking mode (blocks **166,168** of Fig.6B).

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In regard to claim 20, applicant's attention is directed to the algorithms of Fig.7 and 8 which teach the shortening or lengthening, respectively, of the PV delay interval in order to uncover and detect hidden p-waves.

The Lu '192 patent, cited by the applicant as prior art, describes an implantable pacemaker with automatic mode switching whose components read upon applicant's claimed features. See Fig.2. The Lu pacemaker is equipped with an atrial/P-wave sensor **25**, a ventricular/R-wave sensor **35**, atrial and ventricular stimulating circuits **24,34**, respectively, and a control circuit **39**, which performs the function of applicant's comparator, mode switching unit, and cardiac event interval determination units. Applicant's attention is directed to Fig.8, which shows atrial (A-A) comparison functions for identifying an atrial tachycardia. See also Fig.13. The algorithm of Fig.8 utilizes a "predetermined count limit" of K intervals which exceed the A-A interval before declaring an atrial tachycardia. When this limit is reached **404** (Fig.11), the automatic mode switch (AMS) is activated **406**. When AMS is active, a state machine (Fig.4) is pre-programmed to generate fallback pacing rates (col.6, lines 4-7); consequently, through ventricular pace control **50**, the V-V intervals would inherently be affected and set to a fixed rate. As in applicant's claimed device, counters are used to record the number of atrial tachycardia conditions and occurrences of non-tachycardia conditions (Fig.13), and to affect the activation or not of the automatic mode switch (AMS).

In regard to claim 20, applicant's attention is directed to Fig.9, which shows the detection of atrial activity within the blanking period **304**.

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Allowable Subject Matter

10. Claims 13-19 and 21-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

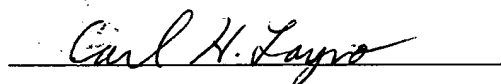
The Hess et al '326 patent recites an implantable pacer capable of mode switching to a "non-tracking" mode of operation upon the detection of atrial arrhythmias (col.9, lines 35-50). Unlike applicant's device, however, the patent does not go into details regarding the functions of equivalent comparator, "mode switching", or "cardiac event interval determination" units.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All faxed correspondence should be sent to the Office's new official FAX number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.

A handwritten signature in cursive script, reading "Carl H. Layno", is written over a horizontal line.

CARL LAYNO
PRIMARY EXAMINER

CHL
2/8/04